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It's Allergy Season Again, Ah-Choo! **Column #106, 4/3/03**

by Jake Mossman, Owner of Taos Pharmacy

The symptoms of seasonal allergies are caused by a reaction to airborne allergens. Up to 1 in 6 Americans are affected by seasonal allergies. Most involve the entire respiratory system, nasal cavity, mouth, throat, bronchi, lungs, and diaphragm. Allergies can be inherited. Children with one parent with allergies have a 50% chance of being allergic and 75% if both parents have allergies. The symptoms are bothersome and in some severe cases debilitating.

Increased mucous production, sneezing, itching (sometimes severe) of the nose, eyes, and throat, headache, sinus pressure, forehead pain, tenderness over the cheekbones, and aching jaws and teeth can all be symptoms of seasonal allergies. Mucous drainage can upset the stomach and cause diarrhea. Secondary ear infections can occur, as the immune system is unable to effectively resist bacterial infection.

Symptoms are caused by the release of histamine, leukotrienes, and peptides from mast cells and basophils. These mediators are released in response to the presence of an immunoglobulin, IgE, which produced upon exposure to pollens.

Minimizing the presence of allergens in the home and work environment can help reduce symptoms. Plastic covers on pillow and

mattresses and minimizing dust accumulation in the home can help. Use of an air purifier or filter can also help.

It is important to drink plenty of fluids, especially water and fresh juices, to keep mucous thin and flowing. Vitamin C can help reduce inflammation by stabilizing mast cells. Plants high in bioflavonoids, such as quercetin, turmeric, rose hips, and bilberry, also help to stabilize mast cells. The protein digesting protein, bromelain, found in pineapples, helps to reduce histamine levels. Tincture of fresh nettles has long been used to reduce allergy symptoms.

We have been impressed by the response to homeopathic preparations in allergy cases. Homeopathic remedies have extremely low incidence of side effects and interactions with other medications. Allergy sufferers who cannot tolerate medication side effects may want to consider using a homeopathic remedy.

Two medications that no longer require prescriptions offer hope to serious allergy sufferers. Nasalcrom®, a cromolyn sodium nasal spray, acts as an intranasal anti-inflammatory to stabilize mast cells. In many cases this medication is effective at preventing allergy symptoms and is virtually free of side effects. Claritin®, a non-sedating **antihistamine** has also recently become available without prescription. Antihistamines have long been the standard of allergy drug therapy but many of them cause severe drowsiness and other anticholinergic side effects. **Loratidine**, found in Claritin®, and the slightly less expensive Alavert®, is the first **antihistamine** that does not cause drowsiness available without a prescription. The greatest drawback to **loratidine** is the price. Hopefully generic versions will follow at a lower cost. Patients should not exceed 10 mg of **loratidine** per day, as antihistamines can cause an irregular heartbeat (**cardiac arrhythmia**) in higher doses.

Allergy symptoms cost Americans much suffering and millions of dollars to treat. Hopefully the measures described here can help you reduce your allergy symptoms.

The pharmacists and staff at Taos Pharmacy are happy to help you with all of your health care problems. Need information? Ask us!

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Assessing Cardiac Safety of Second-generation Antihistamines

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Antihistamines

- First-generation Antihistamines
- Some members of the class (21 CFR 341.12)

- Brompheniramine, Chlorpheniramine, Diphenhydramine, Pyrillamine, Triprolidine
- Association with sedation, decreased psychomotor function, and anticholinergic effects
- Second-generation Antihistamines
- Some members of the class (Drugs 1999; 57: 31)
- Acrivastine, Astemizole, Azelastine, Cetirizine, Ebastine, Fexofenadine, Ketotifen, Loratadine, Mizolastine, Terfenadine
- Some of them are non-sedating or relatively non-sedating, and completely or partly devoid of anticholinergic effects
- Some of them prolong QT interval and cause torsade de pointes

US Marketing History of Second Generation Antihistamines

- Terfenadine ? Withdrawn for **cardiac** safety
- Astemizole ? Withdrawn for **cardiac** safety
- Cetirizine
- Loratadine

. Fexofenadine

PK interaction and QT effects of selected second-generation antihistamines

Drug, dose	PK Interaction with ketoconazole and EES	QTc prolongation w/o interacting drugs	Convincing cases of Tdp
Astemizole,* 10 mg QD	Yes	7 msec (10 mg QD)	Yes
Cetirizine, 5-10 mg QD	None	9.1 msec (20 mg QD)?	No
Fexofenadine, 60 mg BID	Yes (109-164%, AUC0-12hr)	None	No
Loratadine, 10 mg QD	Yes (40-307%, AUC0-24hr)	None	No
Terfenadine,* 60 mg BID	Yes	46 msec (300 mg BID)	Yes
* Withdrawn from US market because of cardiac safety concerns			
? QTc prolongation seen in 1 of 4 studies. In that study, ketoconazole effect on QTc was 8.3 msec, and combined effect of the two was 17.4 msec			
Source: PDR 1997-2000			

Risk Factors for Serious **Cardiac Arrhythmia**

- . Co-administrating of drugs that inhibit hepatic

cytochrome P450 CYP 3A4 enzyme

- . Coadministration of drugs that block delayed rectifier potassium current, I_{Kr}
- . Intentional or accidental overdose
- . Congenital long QT syndrome
- . Ischemic heart disease
- . Congestive heart failure
- . Bradycardia
- . Hepatic dysfunction
- . Renal dysfunction
- . Electrolyte imbalance, such as hypokalemia, hypomagnesemia, hypocalcemia, acidosis
- . Female gender

Assessing **Cardiac** Safety

- . In vivo animal **cardiac** safety studies
- . Whole animal studies in dog, monkey, or other suitable species
- . In vitro tissue studies

- . Electrophysiological study using Purkinje fibers or papillary muscles from established animal species, such as rabbit, guinea pig, dog, or pig
- . Clinical studies
- . Dose escalation and drug interaction **cardiac** safety studies in men and women
- . In vitro ion channel studies
- . Electrical activity in human heart myocytes for channels such as I_{Na} , I_{Ca} , I_{Kr} (HERG), I_{sus} , I_{K1} ,
- . Cloned human channels, such as HERG, $Kv1.5$, expressed in a human cell line

Approvability Considerations

- . Any dose dependent prolongation of **cardiac** repolarization duration by an **antihistamine** and

pharmacokinetic interaction with drugs that can increase its plasma concentration are serious concerns

- Patients at risk of serious **cardiac arrhythmia** and magnitude of QT prolongation that can cause such **arrhythmia** cannot be predicted
- US experience demonstrated failure of label warnings and educational efforts to prevent serious **cardiac arrhythmia** and death due from improper use of some second generation antihistamines
- Any risk for **cardiac arrhythmia** and death with an **antihistamine** is unacceptable because of non-serious nature of the indication - allergic rhinitis, and availability of safer alternatives